



UNITED STATES DEPARTMENT OF COMMERCE
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19128

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/894,788	08/27/97	GIACOMONI	F 05725.0213

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EXAMINER
CHANNAVAJJALA, L

ART UNIT	PAPER NUMBER
1615	<i>20</i>

DATE MAILED: 04/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.
08/894,788

Applicant(s)
Paolo Giacomoni

Examiner
Lakshmi Channavajjala

Group Art Unit
1615

☒ Responsive to communication(s) filed on Feb 9, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 31-38, 40-54, and 56-66 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 31-38, 40-54, and 56-66 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1615

DETAILED ACTION

1. The request filed on 2-9-2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/894,788 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 31-38, 40-54 and 56-66 are currently pending.

Claim Objections

2. Claim 31 is objected to because of the following informalities: on line 3 of claim 31, the word cosmetic is not complete as there is a break in the sentence . Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1615

Claims 31-38, 40-54 and 56-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over

1) Hahn et al in view of Williamson et al; or 2) Hahn et al in view of Wahl et al; or 3) Hahn et al in view of Williamson et al and Wahl et al.

Hahn et al teaches a number of substances which can cause skin irritation, when applied topically. The substances includes vehicles in which active ingredients are formulated (carriers), solvents, detergents, fragrances, propellants, salicylic acid derivatives, retinoids etc., cause irritation which ranges from mild irritation to severe dermatitis conditions. Further, Hahn et al teaches that some people with sensitive skin has an inherent predisposition to skin irritants, for example, people with skin conditions such as psoriasis, contact dermatitis etc., (see col. 3, lines 27-43). Hahn et al teaches the theory that an anti-irritant, to counteract the irritants can be used together with an irritant, in the same composition. However, Hahn et al teaches strontium cation as an anti-irritant in the formulation (see entire document, particularly, cols. 1-4, 10 and 11), and not nitric oxide (NO) synthase inhibitor, as claimed in the instant invention.

Williamson et al teaches various chronic and acute inflammatory conditions such as dermatitis, sunburns, caused by various chemicals and teaches administration of NO synthase inhibitors, methyl-, dimethyl or amino substituted guanidines (column 1-3). Williamson et al also recognizes N-monomethyl-L-arginine, as a NO synthase inhibitor. Williamson et al teaches dermatitis, drug reactions, sunburn, insect bites, burns (thermal, chemical and electrical) (column 3, lines 38-45). Williamson et al also teaches pharmaceutically acceptable diluents and carriers (see col. 11, lines 35-39), which according to Hahn et al are capable of producing skin irritation.

Art Unit: 1615

Accordingly, it is the opinion of the examiner that a skilled artisan would be motivated to incorporate any anti-irritant, in the place of strontium cation in the teachings of Hahn et al, and still be able to counteract the irritation. Because the NO synthase inhibitors of Williamson et al are capable of inhibiting chronic and acute dermatitis, a skin condition caused by chemicals (which according to Hahn et al is caused due to irritation by various chemical substances), a skilled artisan would be motivated to substitute the strontium cation of Hahn et al with NO synthase inhibitors of Williamson et al, with an expectation to inhibit the irritation by any of the above substances of Hahn et al. Williamson does not teach topical application of nitric oxide synthase inhibitor. However, applying nitric oxide synthase inhibitors of Williamson et al as a topical formulation would have been obvious from the teachings of Hahn et al, or alternatively, it is within the scope of a skilled artisan at the time of the instant invention to use topical formulations of nitric oxide synthase inhibitors as first line of choice, with an expectation to produce a local effect.

Wahl et al (hereafter Wahl) teaches treating chronic inflammatory conditions such as psoriasis (paragraph bridging cols. 3 and 4), by administering the specific nitric oxide synthase inhibitors of the instant claims (see col. 3, lines 39-68) by several routes including topical application (col. 6, lines 53-65). Thus Wahl et al teaches the same skin conditions which have a predisposition to be irritated upon exposure to common cosmetic and pharmaceutical products of Hahn et al and suggests topical application of nitric oxide synthase inhibitors. Therefore, it would have been obvious for a skilled artisan at the time of the instant invention to use the nitric oxide

Art Unit: 1615

synthase inhibitors of Wahl in the topical composition of Hahn et al, with an expectation to inhibit the skin irritation caused by the various chemicals (Williamson et al and Hahn et al).

Response to Arguments

4. Applicant's arguments filed 2-9-2000 have been fully considered but they are not persuasive.

Applicants urge that the combination of teachings of Hahn et al and Williamson et al lacks any motivation as the examiner fails to show how to make a particular composition containing an irritant and anti-irritant (or at least a class of anti-irritants) which is obvious. However, it is the examiner's position that the anti-irritant together with the irritants (of Hahn et al), can be taken as a general theory for having an irritant and anti-irritant in the same composition. Strontium of Hahn et al reads on a class of anti-irritants. The motivation to replace the strontium of Hahn et al with the nitric oxide synthase inhibitors of Williamson et al comes from the fact that both the references are directed to teaches the skin conditions such as dermatitis caused by exposure to chemicals and that Williamson et al teaches nitric oxide synthase inhibitors as a treatment. Further, applicants argue that Williamson et al does not teach topical application and instead teaches only oral, intraperitoneal and other routes of administering nitric oxide synthase inhibitors. However, as mentioned above, applying nitric oxide synthase inhibitors of Williamson et al as a topical formulation would have been obvious either from the teachings of Hahn et al or it is within the scope of a skilled artisan at the time of the instant invention to use topical

Art Unit: 1615

formulations of nitric oxide synthase inhibitors as first line of choice, with an expectation to produce a local effect. Further, as discussed above Wahl suggests topical application of the claimed nitric oxide synthase inhibitors. Finally, with respect to the composition claims "topically applied" is a future intended use and carries no patentable distinction.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is (703) 308-2438. The examiner can normally be reached Monday through Friday from 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax number for this Group is (703) 305-5408.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. § 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of confidentiality requirements of U.S.C. § 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703-305-2351)



Lakshmi S. Channavajjala
04/17/2000



Gollamudi S. Kishore, PhD
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